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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/917,710	08/26/1997	DANIEL P. BEDNARIK	1488.0450001	5107

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EXAMINER
WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/917,710	BEDNARIK ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-29,38,39,49-58 and 60-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-29,38,39,49-58 and 60-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The response filed 17 January 2003 (Paper No. 21) has been entered. Claims 1-19, 30-37, 40-48 and 59 have been cancelled. Claims 20-29, 38, 39, 49-58 and 60-73 are being examined in the instant Application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections/Objections

35 U.S.C. § 101/112, first paragraph-, Lack of Utility, Enablement.

Claims 20-29, 38, 39, 49-58 and 60-73 are rejected under 35 U.S.C. 101, as lacking utility. The reasons for this rejection under *35 U.S.C. § 101* are set forth at pp. 4-9 of the previous Office Action (Paper No. 20, 17 October 2002). Claims 20-29, 38, 39, 49-58 and 60-73 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth in the previous Office Action (Paper No. 20, 17 October 2002), one skilled in the art clearly would not know how to use the claimed invention. The claims are directed to the polynucleotides encoding *IL-1R AcM* polypeptide, complementary nucleic acids, vectors comprising the polynucleotides, deposited host cells, and methods of recombinant

expression of the peptide of SEQ ID NO: 2. The specification teaches recombinant expression of *IL-1R AcM* polypeptide and the results of an "Antigenic Index" algorithm (Jameson, et al, 1988, C.A.B.I.O.S, 4: 181-186) applied to the polypeptide sequence of SEQ ID NO: 2.

Applicants arguments (21 Jan 2003, paper 21, p. 1-8) center around several main points: that the proposed use of antibodies (p. 1-3) against *IL-1R AcM* polypeptide enables the instant Invention; that *IL-1R AcM* polypeptide can be used for diagnosis (p. 2) of *IL-1R AcM* - related diseases; that methods needed to perform agonist/antagonist screening assay[s] are described in the Specification and, by implication, are therefore enabling for *IL-1R AcM* polypeptide; that variants (p. 4) of *IL-1R AcM* can be identified; that use of an *antigenic index* algorithm for *IL-1R AcM* polypeptide can be used to ascribe a function to the polypeptide; and that the research papers cited in the last Office Action fail to demonstrate that protein function cannot be predicted from homology to other proteins.

Applicant's arguments, filed 21 Jan 2003 (Paper 21), have been fully considered but they are not persuasive. As discussed in the previous Office Action (p. 4, Paper No. 20, 17 October 2002), no well-established utility exists for newly isolated complex biological molecules. The specification does not disclose experiments that impart *any* specific function for the putative *IL-1R AcM* polypeptide encoded by the claimed nucleotide9s) in the context of the cell or organism. The specification does not teach the skilled artisan how to use the *IL-1R AcM* peptide for any unique or specific purpose.

Applicants further argue against the Utility/Enablement rejection by discussing the usefulness of *IL-1R AcM* polypeptide as a "pharmacological" target of an antibody. For

example, Applicants state: "antibodies directed against *IL-1R AcM* are expected to behave as agonists or antagonist[s] of IL-1 activity" (p. 2, first paragraph, 21 Jan 2003, Paper 21). In fact, specific agonist/antagonist data is precisely the type of evidence that would serve to enable the instant invention. However, it should be kept in mind that usefulness of the antibody will depend on precise characterization of the function of *IL-1R AcM,* which the instant Specification has not done. For example, an enabling disclosure might use antibodies which bind specifically to the *IL-1R AcM* polypeptide, and show evidence of subsequent changes in IL-1 activity. The Examiner agrees that it is reasonable to expect to produce antibodies directed against *IL-1R AcM* polypeptide (p. 2, 21 Jan 2003, Paper 21), or even against fragments of *IL-1R AcM* (p. 5). However, it is not reasonable to expect those antibodies to thereby be agonists or antagonists of IL-1, when it is not known that *IL-1R AcM* interacts with IL-1.

Applicants argue that "[b]ecause the human soluble *IL-1R AcM* polypeptide itself has specific and substantial utility, as discussed above, it is clear that variants which possess 'substantial soluble *IL-1R AcM* polypeptide activity' will possess the same specific and substantial activity" (p. 4). However, specific activities of the *IL-1R AcM* protein and fragments comprising are not disclosed. Since there is no discussion in the instant case as to which particular amino acids are necessary to maintain the functional characteristics of the disclosed polypeptides, the polynucleotides encoding the fragments are not useful. Furthermore, without adequate guidance from the instant Specification, the quantity of experimentation necessary to make and use the entire scope of the polypeptides and polynucleotides specified is enormous. The specification does not teach how to make all polynucleotides encompassed by the Claims, which necessarily would *retain the function* of the *IL-1R AcM* protein.

Applicants argue that the "antigenic index" presented in the instant Specification can be used to identify epitopes of the polypeptide, and is therefore enabling, presumably because antibodies can then be made against *IL-1R AcM.* As discussed above, the Examiner agrees that it is reasonable to expect to produce antibodies directed against *IL-1R AcM* polypeptide (p. 2, 21 Jan 2003, Paper 21), or even to *make* antibodies using an "antigenic index" as a guide to possible epitopes (p. 5). However, it is not reasonable to expect those antibodies to impart a function to *IL-1R AcM* or to be used functionally, when it is not known what the precise function of *IL-1R AcM* actually is.

Applicants then further discuss the papers presented in the last Office Action and argue that homology is predictive of function for a new polypeptide, stating that the publications "describe certain exceptions to the widely recognized principle that, generally, protein function can be predicted based on homology". However, 35 USC § 112, first paragraph, makes clear that the inventor must teach how to use the invention. The Applicant argues that one skilled in the art would know how to use the claimed polynucleotide(s) based on high homology to other polypeptides (e.g., from other species). However, *specific* activities (e.g., unique to the proteins/nucleic acids) of *IL-1R AcM* and the other claimed embodiments are not disclosed. Similarly, concerning the variants *IL-1R AcM,* since there is no discussion in the instant case as to which particular amino acids are necessary to maintain the functional characteristics of the disclosed polypeptides, the polynucleotides encoding the fragments are not useful. Likewise, experiments that demonstrate that the disclosed *IL-1R AcM* polypeptide has a function very similar or the same as that of homologous polypeptides are not disclosed.

Furthermore, the Utility Guidelines make clear that the usefulness of new polynucleotides does not include "entry point" and speculative experiments (Federal Register, 2001, 66: 1094). There is no specific evidence that the protein disclosed in the instant Specification functions as an *IL-1R AcM* polypeptide. However, even if it were established as such, additional specific functional assays would be needed. One skilled in the art would not know the utility and function of the polypeptide disclosed in the instant disclosure, even if it *were* an *IL-1R AcM* protein because, as discussed above, experiments that demonstrate that the disclosed *IL-1R AcM* polypeptide has a function very similar or the same as that of homologous polypeptides are not disclosed.

Conclusion

Claims 20-29, 38, 39, 49-58, 60-73 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW
4/18/03

Gary L. Kunz
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